PATENT
Attorney Docket No.: 10139-02002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
FRIGG et al.	)	
	)	
Serial No.: 10/532,909	)	Group Art Unit: 3775
	)	
Filed: December 16, 2005	)	Examiner: N. Woodall
	)	
For: DEVICE FOR THE TREATMENT OF FRACTURES OF THE FEMUR	)	
	)	
Confirmation No.: 3108	)	

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed on March 16, 2009, and pursuant to 37 C.F.R. § 41.37, Appellants presents this appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 19-40 in the Final Office Action dated November 18, 2008.

The appealed claims are set forth in the attached Claims Appendix.

1. Real Party in Interest

This application is assigned to Synthes USA, LLC, which is a subsidiary of Synthes, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 1-18 have been canceled, and claims 19-40 have been rejected in the final Office Action. Claims 19-40 are the subject of this appeal.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The following summary refers to the specification and identifies certain claim limitations with the reference characters of one or more drawings. The association in this summary of a claim limitation with a particular reference character, figure, or passage from the specification is only exemplary and is not intended to limit the scope of the claims.

The present invention, as exemplified in claim 19, is directed to a device for the treatment of femoral fractures that includes an intramedullary pin (1) having a first longitudinal axis (2), a proximal portion (4), a distal portion (3), and at least one transverse opening (5) through the proximal portion of the pin (1). (Specification at page 6, lines 7-10 ; Figure 1). The transverse opening (5) has a non-circular cross-section and forms an oblique angle with the first longitudinal axis (2). (Specification at page 6, lines 7-10; Figure 1). The device also includes a bone fixation element (20) having a second longitudinal axis (21); the bone fixation element has a shaft (24), an end of which is configured and dimensioned to engage bone in the femoral head. (Specification at page 6, lines 16-20; Figure 1). Another part of the device is a sliding sleeve (10). (Specification at page 6, line 2; Figure 1). The sliding sleeve (10) includes a central bore (13) that receives the shaft (24) of the bone fixation element (20) while permitting free rotation of the bone fixation element (20) relative to the sleeve (10). (Specification at page 7, lines 10-13 and lines 19-21; Figure 2). An external surface profile of the sleeve (10) has at least a portion with a non-circular cross-section adapted to mate with the non-circular cross-section of the transverse opening (5); the mating prevents the sleeve (10) from rotating with respect to the pin (1). (Specification at page 7, lines 22-25; Figure 2). The device also includes a locking element (30) that selectively locks rotation of the bone fixation element (20) relative to the sleeve (10) when in a first position, and that permits free rotation of the bone fixation element (20) relative to the sleeve (10) when in a second position. (Specification at page 6, line 30, to page 7, line 4; Figures 1 and 6).

The present invention, as exemplified by claim 37, is directed to a device for the treatment of femoral fractures that includes an intramedullary pin (1) and a cross member. The pin (1) includes a first longitudinal axis (2), a proximal portion (4), a distal portion (3), and at least one transverse opening (5) through the proximal portion (4), with the transverse opening (5) forming an oblique angle with the first longitudinal axis (2). (Specification at page 6, lines 7-10; Figure 1). The cross member includes a sliding sleeve (10), a bone fixation element (20), and a locking mechanism (30). (Specification at page 6, lines 1-4; Figure 1). The sliding sleeve (10) includes a central bore (13), a circular interior surface profile (see Figure 2), and a non-circular exterior surface profile (See Figure 2). (Specification at page 6, lines 11-14). The exterior surface profile of the sliding sleeve (10) mates with the non-circular profile of the transverse opening (5), thereby preventing rotation of the sleeve (10) with respect to the pin (1). (Specification at page 7, lines 22-25; Figure 2). The bone fixation element (20) includes a shaft (24) and an end (23) configured and dimensioned to engage bone in the femoral head. (Specification at page 6, lines 16-20; Figure 1). The shaft (24) is configured and dimensioned for free rotation within the central bore (13) of the sliding sleeve (10). (Specification at page 7, lines 10-13 and lines 19-21; Figure 2). The locking mechanism (30) is configured and adapted to selectively lock rotation of the bone fixation element (20) relative to the sleeve (10) when in a first position, and to permit free rotation of the bone fixation element (20) relative to the sleeve (10) when in a second position. ((Specification at page 6, line 30, to page 7, line 4; Figures 1 and 6).

6. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 19-25, 27, 31, 34-38, and 40 are unpatentable under 35 U.S.C. § 103(a) over United States Patent No. 5,032,125 to Durham ("Durham") in view of United States Patent No. 5,454,813 to Lawes ("Lawes").

II. Whether claim 27 is unpatentable under 35 U.S.C. § 103(a) over Durham in view of Lawes and United States Patent No. 6,648,889 to Bramlet et al. ("Bramlet").

III. Whether claims 28 and 29 are unpatentable under 35 U.S.C. § 103(a) over Durham in view of Lawes and United States Patent No. 4,432,358 to Fixel ("Fixel").

IV. Whether claims 30, 32, and 39 are unpatentable under 35 U.S.C. § 103(a) over Durham in view of Lawes and United States Patent No. 5,908,422 to Bresina ("Bresina").

V. Whether claim 33 is unpatentable under 35 U.S.C. § 103(a) over Durham in view of Lawes, Bresina, and United States Patent No. 6,187,007 to Frigg et al. ("Frigg").

7. Argument

I. The Durham-Lawes Rejection

Claim 19 recites a device for the treatment of femoral fractures comprising an intramedullary pin having "at least one transverse opening through the proximal portion...forming an oblique angle with the first longitudinal axis and having a non-circular cross-section" and "a bone fixation element having a...first end configured and dimensioned to engage bone in the femoral head" in combination with "a sliding sleeve having a central bore, an interior surface profile, and an exterior surface profile, *the central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve*, and the exterior surface profile having at least a portion with a non-circular cross-section adapted to mate with the non-circular cross-section of the transverse opening, thereby prevention rotation of the sleeve with respect to the intramedullary pin" and "*a locking mechanism configured and adapted to selectively lock rotation of the bone fixation element relative to the sleeve when in a first position and permit free rotation of the bone fixation element relative to the sleeve when in a second position.*"

It is respectfully submitted that Durham fails to teach or suggest a sliding sleeve with "a central bore and interior surface profile configured to receive the shaft of the bone fixation element *while permitting free rotation of the bone fixation element relative to the sleeve*," as

recited in claim 19. Rather, Durham shows a system with a sleeve 40 which is rotatable relative to the intramedullary rod 20 and a lag screw 60 which is keyed to an interior of the sleeve 40 to prevent rotation of the lag screw 60 relative to the sleeve 40. (*See* Durham, col. 4, ll. 3 - 6; Fig. 1). This is the opposite of the claimed arrangement and necessitates an additional set screw 80 inserted longitudinally through the intramedullary rod 20 to engage a surface of the sleeve 40 and lock it against rotation after it has been properly positioned. (*See* Durham, col. 4, li. 58 - col. 5, li. 11; Fig. 1) The selection of the keyed surfaces of the lag screw 60 and the interior of the sleeve 40 of Durham are clearly more than mere design choices as they impact multiple steps in the procedure for implanting the system. Specifically, in contrast to the claimed apparatus, the lag screw 60 of Durham can not be inserted while received within the sleeve 40. (*Id.*). The lag screw 60 is first rotatably inserted through the intramedullary rod 20 to a desired position in the femur. The sleeve 40 is slid over a shaft of the lag screw 60 only after the lag screw 60 has been inserted to the desired position because if it were present during insertion of the lag screw 60, the lag screw 60 would not be able to rotate as required. The sleeve 40 is then locked in position by insertion of a set screw 80 longitudinally through the intramedullary rod 20 to engage ridges 50 formed on the sleeve 40. (*Id.*). The Examiner's proposed modification completely alters every one of these steps and is clearly far more than a mere design choice. None of these proposed changes is in any way described or suggested in Durham or in any of the other cited references and it is submitted that the Examiner's rejection is an improper hindsight reconstruction of the invention the only motivation for which is the disclosure of the present application.

In the Final Office Action, the Examiner also indicates that Durham only indicates "that the device may include engagement surfaces to perform the function if so desired, which means that the device does not have to include the engagement surfaces and therefore may not be included in the device." (*See* 11/18/08 Office Action, p. 8). The only support the Examiner has relied on for this assertion is the premise that the detailed description of Durham describes preferred embodiments only and does not describe every possible variation of the device. However, it is respectfully submitted that such flimsy support can not serve to justify structural changes to a system which require radical changes to the medical procedure required to use the system. Clearly any change to the method of use of a surgical implant is a significant change and not, as the Examiner stated, a matter of mere design choice. It is therefore respectfully submitted that the modification proposed by the Examiner constitutes an improper hindsight reconstruction of the Durham and that this rejection should be withdrawn.

Lawes does not cure the above mentioned deficiencies of Durham. It is therefore respectfully submitted that Durham and Lawes, taken alone or in any combination, do not teach or suggest a sliding sleeve with a "central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve," as recited in claim 19 and that claim 19 is therefore allowable. Because claims 20 - 25, 27, 31 and 34 - 36 depend from and therefore include all of the limitations of claim 19, it is respectfully submitted that these claims are also allowable.

Claim 37 recites limitations substantially similar to those of claim 19 including "a sliding sleeve having a central bore, a *circular interior surface profile*, and a non-circular exterior surface profile" in combination with a "*shaft configured and dimensioned for free rotation within the central bore of the sliding sleeve*." Therefore, it is respectfully submitted that claim 37 is also allowable over Durham and Lawes for at least the same reasons previously mentioned with regard to claim 19. Because claims 38 and 40 depend from and therefore contain all the limitations of claim 37, it is respectfully submitted that these claims are also allowable.

Similarly, all the dependent claims listed in this rejection are patentable for at least the same reasons given above.

II. The Durham-Lawes-Bramlet Rejection

Claim 27 depends from and therefore includes all of the limitations of claim 19. As discussed above, Durham and Lawes fail to teach or suggest a sliding sleeve with a "central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve," as recited in claim 19. It is further submitted that Bramlet fails to cure the above-noted deficiency of Durham and Lawes. It is therefore submitted that Durham, Lawes and Bramlet, taken alone or in any combination, fail to teach or suggest the recited limitations of claim 19. Because claim 27

depends from and therefore includes all of the limitations of claim 19, it is respectfully submitted that this claim is also allowable.

III. The Durham-Lawes-Fixel Rejection

Claims 28 and 29 depend from and therefore include all of the limitations of claim 19. As discussed above, Durham and Lawes fail to teach or suggest a sliding sleeve with a "central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve," as recited in claim 19. It is further submitted that Fixel fails to cure the above-noted deficiency of Durham and Lawes. It is therefore submitted that Durham, Lawes and Fixel, taken alone or in any combination, fail to teach or suggest the recited limitations of claim 19. Because claims 28 and 29 depend from and therefore include all of the limitations of claim 19, it is respectfully submitted that these claims are also allowable.

IV. The Durham-Lawes-Bresina Rejection

Claims 30 and 32 and claim 39 depend from and therefore include all of the limitations of claims 19 and 37, respectively. As discussed above, Durham and Lawes fail to teach or suggest a sliding sleeve with a "central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve," as recited in claim 19 and "a circular interior surface profile, and a non-circular

exterior surface profile" in combination with a "shaft configured and dimensioned for free rotation within the central bore of the sliding sleeve," as recited in claim 37. It is further submitted that Bresina fails to cure the above-noted deficiencies of Durham and Lawes. It is therefore submitted that Durham, Lawes and Bresina, taken along or in any combination, fail to teach or suggest the recited limitations of claims 19 and 37. Because claims 30 and 32 and claim 39 depend from and therefore includes all of the limitations of claims 19 and 37, respectively, it is respectfully submitted that these claims are also allowable.

V. The Durham-Lawes-Bresina-Frigg Rejection

Claim 33 depends from and therefore includes all of the limitations of claim 19. As discussed above, Durham and Lawes fail to teach or suggest a sliding sleeve with a "central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve," as recited in claim 19. It is further submitted that Bresina and Frigg fail to cure the above-noted deficiency of Durham and Lawes. It is therefore submitted that Durham, Lawes, Bresina and Frigg, taken alone or in any combination, fail to teach or suggest the recited limitations of claim 19. Because claim 33 depends from and therefore includes all of the limitations of claim 19, it is respectfully submitted that this claim is also allowable.

8. Conclusions

For the reasons set forth above, Appellants respectfully requests that the Board reverse the final rejection of the claims by the Examiner and indicate that all pending claims are allowable.

Respectfully submitted,

Date: May 18, 2009

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CLAIMS APPENDIX

19. (Previously presented) A device for the treatment of femoral fractures comprising:

an intramedullary pin having a first longitudinal axis, a proximal portion, a distal portion, and at least one transverse opening through the proximal portion of the pin, the at least one transverse opening forming an oblique angle with the first longitudinal axis and having a non-circular cross-section;

a bone fixation element having a second longitudinal axis, a first end, a second end, and a shaft, the first end configured and dimensioned to engage bone in the femoral head,

a sliding sleeve having a central bore, an interior surface profile, and an exterior surface profile, the central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve, and the exterior surface profile having at least a portion with a non-circular cross-section adapted to mate with the non-circular cross-section of the transverse opening, thereby prevention rotation of the sleeve with respect to the intramedullary pin; and

a locking mechanism configured and adapted to selectively lock rotation of the bone fixation element relative to the sleeve when in a first position and permit free rotation of the bone fixation element relative to the sleeve when in a second position.

20. (Previously presented) The device of claim 19, wherein the bone fixation element, sliding sleeve and locking mechanism are adapted for insertion through the transverse opening in the pin as a single preassembled unit.

21. (Previously presented) The device of claim 19, wherein the second end of the bone fixation element includes a longitudinal bore.

22. (Previously presented) The device of claim 21, wherein the longitudinal bore at the second end of the bone fixation element is at least partially threaded.

23. (Previously presented) The device of claim 22, wherein the locking mechanism is a fixing screw having a screw head with a diameter D and a screw shank with a diameter d having an outside thread, where D>d.

24. (Previously presented) The device of claim 23, wherein the outside thread of the fixing screw shank corresponds to the threaded bore of the bone fixation element, and progressive tightening of the fixing screw within the threaded bore rotationally locks the bone fixation element with the sliding sleeve, thereby preventing rotation of the bone fixation element relative to the sliding sleeve.

25. (Previously presented) The device of claim 19, wherein the bone fixation element is axially fixed relative to the sliding sleeve.

26. (Previously presented) The device of claim 25, wherein the shaft of the bone fixation element includes a first annular groove and the internal surface profile of the sliding sleeve includes a second annular groove, and a ring element engages both the first and second annular grooves to prevent axial displacement of the shaft relative to the sliding sleeve.

27. (Previously presented) The device of claim 19, wherein a rear end of the sliding sleeve extends a distance x past the second end of the bone fixation element, where x is at least 0.01 mm.

28. (Previously presented) The device of claim 19, wherein the second end of the bone fixation element includes an externally threaded portion.

29. (Previously presented) The device of claim 28, wherein the locking mechanism is a nut with an internal thread that corresponds to the externally threaded portion at the second end of the bone fixation element.

30. (Previously presented) The device of claim 19, wherein the first end of the bone fixation element includes a helical blade.

31. (Previously presented) The device of claim 19, wherein the first end of the bone fixation element includes a screw thread, a chisel, a pin, a T-section or a double T-section.

32. (Previously presented) The device of claim 19, wherein the first end of the bone fixation element includes a plurality of helical blades.

33. (Previously presented) The device of claim 30, wherein the helical blade has a pitch of at least 50 mm.

34. (Previously presented) The device of claim 19, wherein the locking mechanism is adapted to limit axial displacement of the sliding sleeve relative to the intramedullary pin.

35. (Previously presented) The device of claim 19, wherein the bone fixation element is a screw.

36. (Previously presented) The device of claim 19, wherein the external surface profile of the sliding sleeve includes a longitudinal projection that mates with a longitudinal recess in the transverse opening.

37. (Currently amended) A device for the treatment of femoral fractures comprising:

an intramedullary pin having a first longitudinal axis, a proximal portion, a distal portion, and at least one transverse opening through the proximal portion of the pin, the at least one transverse opening forming an oblique angle with the first longitudinal axis and having a non-circular cross-section;

a cross-member configured for insertion through the transverse opening to engage bone in the femoral head, the cross-member including:

a sliding sleeve having a central bore, a circular interior surface profile, and a non-circular exterior surface profile, the exterior surface profile adapted to mate with the non-circular cross-section of the transverse opening, thereby preventing rotation of the sleeve with respect to the intramedullary pin,

a bone fixation element having a first end, a second end, and a shaft, the first end configured and dimensioned to engage bone in the femoral head, and the shaft configured and dimensioned for free rotation within the central bore of the sliding sleeve, and

a locking mechanism configured and adapted to selectively lock rotation of the bone fixing element relative to the sleeve when in a first position and permit free rotation of the bone fixing element relative to the sleeve when in a second position.

38. (Previously presented) The device of claim 37, wherein the cross-member is adapted for insertion through the transverse opening in the pin as a single preassembled unit.

39. (Previously presented) The device of claim 37, wherein the first end of the bone fixation element includes a helical blade.

40. (Previously presented) The device of claim 37, wherein the bone fixation element is a screw.

EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.